

REMARKS

After entry of this Response, Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are pending. Claims 1, 38, 39 and 59 are amended herein. New Claim 72 is added. Support for these amendments and new claim can be found in the language of the original claims and throughout the specification. It is believed that no new matter is added. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are under consideration. In light of the following remarks, Applicants respectfully request reconsideration of this application, entry of this Amendment, and allowance of the claims to issue.

**REJECTION OF CLAIMS 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, & 61-71
UNDER 35 USC 112, 2ND ¶**

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-71 were rejected under 35 USC 112, 2nd paragraph as being indefinite for use of the phrase “substantially where the catalyst is present”. Applicants have amended independent Claims 1, 38, and 39 to reflect that the reaction between the catalyst and the second reactant forms oxygen gas which is deliverably contained within closed cells formed in the polymeric matrix. The Examiner’s questions are rendered moot by the amendments, and Applicants respectfully submit that the currently amended claims are not indefinite.

REJECTION OF CLAIMS 1, 2, 4, 6, 8, 21-28, 31-35, AND 38-71 UNDER 35 U.S.C. § 103

Claims 1, 2, 4, 6, 8, 21-28, 31-35, and 38-71 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Murdock, U.S. publication 2002/0042587 (“the ‘587 publication”), in view of Marans, U.S. Patent No. 3,511,764 (“the ‘764 patent”), and Ladin, U.S. Patent No. 5,792,090 (“the ‘090 patent”).

The Office Action states that even though “product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.” Applicants respectfully submit that the product of Applicants’ invention is not taught or suggested by the cited references, individually or in combination, and that the cited references cannot be combined to result in Applicants’ currently claimed invention that delivers oxygen from closed cells within a polymeric matrix.

Determining the scope and contents of prior art

1. The Office Action states that the '587 publication teaches "polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors." The Office Action states that the "foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen."

What is not noted in the Office Action characterization of the reference is that the closed cells containing gasses are inert and the gas does not exit the closed cell. "The gas bubbles act as an inert filler, increasing the surface area of the matrix without introducing the drawback of common "inert" fillers, such as glass beads, titanium dioxide, quartz powder, polymer powders, etc., to which therapeutically active agents may bind." Paragraph 37, the '587 publication.

2. The Office Action states that the '764 patent teaches cross-linked polyacrylamide foam that is "foamed by decomposition product of another polymer during manufacture of the polymer to provide uniform closed cell foam matrix that swells and absorbs water but not dissolve. Foaming of polyacrylamide was performed during the manufacture of the polyacrylamide crosslinked polymer."

What is not noted in the Office Action characterization of the '764 patent is that the article taught is cross-linked polyacrylamide that is foamed by the decomposition product of polyoxymethylene, which results from the polymerization of acrylamide and trioxane. See Col. 1, lines 13-14, line 39, and lines 57-58. The foamed product formed is "useful as a packing material, insulation, water absorption material" and there is no teaching or suggestion that the gaseous polyoxymethylene decomposition product is released from the matrix. See Col. 4, lines 5-7.

3. The Office Action states that the '090 patent teaches a dressing that "comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes. The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen."

What is not noted in the Office Action characterization of the '090 patent is that no closed cells containing oxygen are formed in the foam of the '090 patent, and that the dressing of the '090

patent is designed to intermittently generate oxygen in situ for brief periods and the oxygen is immediately provided to the wound. See Col. 4, lines 15-18, Col. 3, lines 30-33, the '090 patent.

The Office Action concedes that the '587 publication does not teach the chemical reaction that produces the gas in the foam, as claimed in currently pending Claims 1, 38 and 39. The Office Action also concedes that the '587 publication does not teach polyacrylamide polymer as recited in Claims 1, 38 and 39. But, the Office Action concludes that "at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically in the foam as taught by Murdock." Applicants' respectfully point out that the '587 publication is directed to providing a reservoir for an electrotransport drug delivery system, not a wound treatment device or an oxygen delivery device. The "foam as taught by Murdock" is to reduce the drug loading volume of the reservoir without reducing the reservoir size or volume. See the '587 publication, paragraph 12. The closed cells are space filling only; they are inert and do not deliver the enclosed gas. Therefore, the closed cells in the "foam as taught by Murdock" do not function like the currently claimed invention; thus, the "foam as taught by Murdock" is physically and functionally different from Applicants' currently claimed invention.

The Office Action states that it would have been obvious "to provide polymeric cross-linked closed cell foam wound dressing containing oxygen that can be produced chemically as disclosed by Murdock [the '587 publication] and replace the closed cell cross-linked polymer foam with cross-linked polyacrylamide closed cell foam taught by Marans [the '764 patent]." This combination of references does not result in a teaching or suggestion of Applicants' currently claimed invention, nor does this statement accurately reflect the teaching of the references. Applicants interpret the quote above to mean that the oxygen is produced chemically and is found in a polymeric cross-linked closed cell foam like the foam taught by the '587 publication, and not that the '587 publication teaches chemical methods for making foams of closed cells containing oxygen. Applicants submit that the combination of the space-filling closed cells foam reservoir of the '587 publication with the cross-linked polyacrylamide closed cell foam made by the decomposition of polyoxymethylene of the '764 patent does not teach or suggest Applicants' currently claimed invention. The closed cells formed in the '764 patent and the '587 publication do not deliver the gas contained within the closed cells, and therefore, even if the combination

could be accomplished to yield a product, the combination does not deliver the gas of the closed cells. Both of the references teach inert closed cells that do not change or interact with the environment, and if the closed cells of either reference did interact with the environment and lose the entrapped gas, the volume of the closed cells would be reduced and the product of each reference would no longer be fit for its intended use.

It is the burden of the Office to provide a rationale from the prior art for making the specific claimed modification or combination. The Office Action states that the combination is motivated because the '764 patent teaches "that cross-linked polyacrylamide closed cell foam can absorb water without dissolving and one would have been motivated to form the bubbles in the crosslinked polymer during the manufacture of the crosslinked polymer because Marans teaches that such process provides a uniform foam. One would have reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that can be produced chemically wherein the foam is uniform and absorbs water without dissolving." The "uniform foam" of the '764 patent results from irradiating and heating of an acrylamide and a trioxane, and a higher heating step to decompose the polyoxymethylene formed from the trioxane. The inert closed cells of the '587 publication result from stirring or whipping a polymer liquid to introduce bubbles and then cross-linking the polymer. The combination of these two teachings would result in introducing bubbles into the acrylamide and trioxane mixture by whipping or stirring (the teaching of the '587 publication), irradiating and heating to polymerize the bubbled mixture, if this is possible in the presence of the gas introduced into the mixture, and then heating further to decompose the polyoxymethylene and forming a confused jumble of bubbles in the polymeric material. Alternatively, the mixture, which may or may not be polymerizable, is not heated the second time, and the polyoxymethylene would remain within the matrix, and would be a contaminating factor. No matter how one combines these two references, any closed cells that result would still not deliver the gas contained within the closed cells. The combination of the '587 publication and the '764 patent does not result in the invention of Applicants' currently pending claims.

The Office Action continues by stating "[a]dditionally, it would have been obviousto produce the crosslinked polyacrylamide closed cell foam containing oxygen in the bubbles as

disclosed by the combination of Murdock [the ‘587 publication] and Marans [the ‘764 patent] and further produce the oxygen during the formation of the foam by the reaction of hydrogen peroxide and catalyst as disclosed by Ladin.” The closed cell foam “disclosed by the combination of Murdock [the ‘587 publication] and Marans [the ‘764 patent]” as discussed in the previous paragraph does not result in a workable product and does not result in a product that delivers the contents of the closed cells. Where in the method of the ‘764 patent would a catalyst be added? Is the catalyst added to the liquid and the hydrogen peroxide added to the liquid? Does any oxygen evolved interfere with the polymerization? What effect does the irradiation and heating have on the catalyst or the hydrogen peroxide? Is the hydrogen peroxide added, before or after the second heating step to decompose the polyoxymethylene? What effects does polyoxymethylene have on a catalyst or hydrogen peroxide? Not only would the cited references not lead one to consider these questions, the answers to such questions are not obvious from the teachings of the references. The teaching of the combination of the ‘587 publication and the ‘764 patent are that the closed cells are inert and no gas leaves the closed cells, so even if the closed cells contained oxygen made chemically as taught by the ‘090 patent, the oxygen would not be released.

The Supreme Court recently addressed nonobviousness of “combination” inventions in *KSR Int'l Co. v. Teletex. Inc.*, 127 S. Ct. 1727 (2007) (*KSR*). The Court confirmed that it is legally insufficient to merely point to the various recited elements. Instead, the Office must identify the basis for the alleged modification or combination by one of ordinary skill to arrive at the claimed invention.

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR at *37-*38 (emphasis by underlining added).

Moreover, the Supreme Court opined that conclusory statements cannot provide an adequate basis for the alleged modification or combination; the reasoning must be explicit. A combination of the cited references in the present application yields an unworkable solution, and cannot provide the basis for the modification or combination, and the reasoning provided for the combination is not explicit.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

KSR at *36-*37 (emphasis by underlining added).

Absent this explicit reasoning to support the basis for the modification or combination, the alleged modification or combination cannot support a *prima facie* obviousness rejection for the reasons discussed herein, particularly in view of the fact that no combination of the references yields closed cells that deliver oxygen.

The Supreme Court has reaffirmed the Graham factors for determination of obviousness under 35 U.S.C. 103(a) in *KSR*. The four factual inquiries under *Graham* require examination of: (1) the scope and contents of the prior art; (2) the differences between the prior art and the claims in issue; (3) the level of ordinary skill in the pertinent art; and (4) the objective evidence of secondary considerations. *Graham v. John Deere (Graham)*, 383 U.S. 1, 17-18, 149 USPQ 459, 467 (1966); see also 35 U.S.C. § 103 (2000).

The Court has further recognized that the requirement for a teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, which was established by the Court of Customs and Patent Appeals, provides a helpful insight for determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). In addition, the Court maintained that any analysis supporting a rejection under 35 U.S.C. § 103(a) should be made

explicit, and that it is "important to identify reasons that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed, because "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR* at 14, 15.

Further, courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in art, to modify the reference or combine the references' teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all of the claim limitations. See e.g., *In re Dembiczaik*, 175 F.3d 994 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Applicants submit that the '587 publication teaches "foaming a polymeric solution", and not foaming a cross-linked polymeric network (¶ 32 and 36). The '587 publication teaches the formation of a foamed polymeric solution "by extrusion spraying, frothing, compression molding, injection molding, sintering, leaching, or the like. Foam formation may be accomplished by stirring a polymer solution with a high speed, high sheer mixing apparatus and or by an apparatus that injects gas into a solution of the polymer." (¶ 36). The '587 publication also teaches preparation of "a foamed polymer [solution] by decompression expansion [, wherein] a solution of a volatile blowing agent in molten polymer is formed in an extruder under pressure." (¶ 38). The '587 publication also teaches a foam that can be made by a "frothing process[, which] involves dispersing a gas in a fluid that has surface properties suitable for producing a foam. After formation of the foam, it can be, permanently stabilized by crosslinking." (¶ 39). The '587 publication teaches the "dimensional stability [of the polymer solution with the incorporated gas] is achieved upon cooling or other cross-linking methods." (¶ 38). Therefore, in the embodiments taught by the '587 publication, the gas of the polymer matrix in the '587 publication is introduced into the composition when the polymer solution is a liquid, and before the polymer solution is cross-linked.

The Office Action states that “US ‘587 teaches polymeric cross-linked foam reservoir comprising cross-linked polymer and closed cell containing oxygen that can be produced chemically. US ‘587 suggests chemical formation of gas in the closed cells.” See Office Action, p. 10. Though no reference is given for this suggestion by the ‘587 publication, the ‘587 publication states at paragraph 36 that “Foaming a polymer matrix may be accomplished by any chemical or physical method known in the art.” But regardless of the method, the foaming method is limited by chemical and physical requirements. As argued previously, polyacrylamide does not effectively polymerize in the presence of oxygen; thus, a liquid composition of polyacrylamide cannot be simply bubbled with a chemical reaction that forms oxygen, as in the method of the ‘587 publication. A simple substitution of polyacrylamide from the ‘764 patent cannot be made in the ‘587 publication method, nor can the method of foaming taught by the ‘764 patent have a simple replacement of oxygen in the closed cells of polyoxymethylene. As previously noted, the closed cells taught by the ‘764 patent and the ‘587 publication are inert and no delivery of gas occurs; thus, the combination of the cited references does not yield the invention of Applicants’ currently pending claims.

Applicants are not arguing for a rigid application of the teaching-suggestion-motivation (TSM) rationale, which requires that a printed statement to be present for a finding of obviousness. Applicants submit that the Supreme Court acknowledged that the TSM test was one of a number of valid rationales that could be used to determine obviousness. *KSR* at 1727 (2007); see MPEP 2141; *In re Kahn*, 441 F.3d 977, 986, 78 U.S.P.Q. 2d 1329, 1335 (Fed. Cir. 2006). Applicants respectfully submit that there is no suggestion or motivation to make the proposed modification of a polyacrylamide polymer of the ‘764 patent in the foam of the ‘587 publication, and in fact, the ‘587 publication teaches away from use of polyacrylamide by requiring the gas be introduced into a liquid polymer solution prior to the cross-linking of the polymer solution.

Modification of the ‘587 publication by implementation of polyacrylamide polymer to create a polyacrylamide foam matrix as taught in the ‘764 patent would render the ‘587 publication unsatisfactory for its intended purpose. Modification of the ‘764 patent by implementation of the method of the ‘587 publication would render the ‘764 patent unsatisfactory for its intended purpose. The modification of the addition of the production of oxygen as taught by the ‘090 patent to either the ‘764 patent or the ‘587 publication, individually or in combination, does not result in a

product that is satisfactory for its intended purpose. According to the U.S. Court of Appeals for the Federal Circuit, “[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed invention.” (*In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 125 (Fed. Cir. 1984); see MPEP 2143.01. See *In re Fritch*, 972 F.2d 1260, 1265 n.12, 23 U.S.P.Q.2d 1780, 1783 n.12 (Fed. Cir. 1992) (“This court has previously found a proposed modification inappropriate for an obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purpose.”) (citing *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984)); *Schneider (Europe) AG v. Scimed Life Sys., Inc.*, 852 F. Supp. 813 (D. Minn. 1994) (“Where obviousness is based upon a modification of a reference that destroys the intended purpose or function disclosed in a reference, there is no motivation for engaging in the modification.”) (citing *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984)). Further, the intended purpose of the closed cell foams of the ‘587 publication and the ‘764 patent are that the closed cells are inert and the foam product maintains its structure by not delivering the gas contained within the closed cells. There is no teaching of a modification of any of the cited references to render the closed cells of the cited references anything other than to be inert, and if such a modification is attempted, it would render the combined references unsatisfactory for their intended purposes. As a result, Applicants respectfully request the Examiner to withdraw this rejection.

The Office Action, p. 13, states that “If the prior art structure is capable of performing the intended use, then it meets the claim. US ‘587 is directed to wound treatment as intended by the present invention.” Applicants respectfully submit that the prior art structure, either that of the ‘587 publication or the ‘764 patent, is incapable of delivering a gas from its closed cells, and if either of them suffered a loss of gas from the closed cells, with the concomitant loss of volume of the closed cells, the entire function of the structure would be destroyed. Applicants’ currently claimed invention is an oxygen delivery device, wherein oxygen is present in closed cells, and the oxygen can be delivered from the closed cells, and the volume of the closed cells is reduced. Thus, there are functional and physical differences between the cited references and Applicants’ currently claimed invention.

The combination of the cited references to include the elements of the present invention requires hindsight reasoning, which the Federal Circuit has explicitly rejected. See *In re Fritch*, at 1260 ("Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious."). Without hindsight, independent Claims 1, 38 and 39 would not be rejected as obvious by the disclosures and teachings of the '587 publication, the '764 patent and the '090 patent. Likewise, the claims that depend from independent Claims 1, 38, and 39 would not be rejected as obvious. See *In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988) ("Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.").

One must be mindful of the repeated warnings of the Supreme Court as to the danger of hindsight bias. See, e.g., *Graham*, 383 U.S. at 36 (consideration of secondary factors "serve[s] to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue" (internal quotations and citations omitted)); *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) ("[T]he very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." (internal quotations omitted)). Applicants submit that hindsight is being used to combine terms that are found in the prior art, without a consideration of the physical and chemical realities of the terms, to try to reach a teaching or suggestion of Applicants' currently claimed invention. Applicants respectfully request the Examiner to withdraw this rejection.

The Office Action continues to maintain that the physical and chemical characteristics of the references can be overlooked for a product-by process claim, because "it has been held that it is *prima facie* obvious to reverse the order of the prior art process steps" and...."selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix." The Office Action fails to consider that reversing the order of steps may be possible if the order of steps is not important to the result or are not limited by the chemical or physical nature of the components used in the method.

Formation of a polyacrylamide matrix with closed cells containing oxygen wherein the oxygen is delivered from the closed cells occurs if the polyacrylamide matrix is first cross-linked, and oxygen is introduced into the matrix following cross-linking of the polyacrylamide polymers, and the resulting closed cells deliver the oxygen found within the closed cells. The cited references never teach a method for making closed cell foams where the gas is delivered from the closed cells. Adding the oxygen first and then cross-linking the polymers is not chemically possible for polyacrylamide, and if another polymer is used, as in the '587 publication, the cells produced do not deliver the gas. Replacing polyoxymethylene with oxygen in the '764 patent cannot be accomplished using the methods taught by the '764 patent, and merely stating that it can be done is not the standard for obviousness. According to MPEP § 2113, *In re Garnero* states that "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." 412 F.2d 276, 279 (C.C.P.A. 1979) (emphasis added); See MPEP § 2113. In Applicants' currently claimed invention where the polymeric matrix comprises polyacrylamide, the step of cross-linking must occur prior to the addition of oxygen, and a teaching of gas incorporation prior to cross-linking is not relevant. Additionally, only in Applicants' claimed invention do the closed cells deliver the gas, and not in the teachings of the cited references. Given the technical limitations associated with cross-linking polyacrylamide in the presence of oxygen, the manufacturing process steps imparting distinctive structural characteristics to the final product and must be considered when assessing the patentability of the claims. The statements of the Office Action cited for supporting *prima facie* obviousness are not applicable to the currently pending invention. Therefore, Applicants respectfully request the Examiner to withdraw this rejection.

The foregoing is a complete response to the Office Action dated June 4, 2009. Applicants respectfully submit that at least Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-71, and 72 are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not

concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicants respectfully request the Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

**ATTORNEY DOCKET NO.: 01307.0003U2
APPLICATION NO.: 09/752,939**

A Credit Card Payment submitted via EFS in the amount of \$1,110.00 (for a three (3) month extension of time fee for a large entity) and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (678) 420-9332 is respectfully solicited.

Respectfully submitted,

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